

#### DEPARTMENT OF HEALTH & HUMAN SERVICES

#### PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive B MSC 7982
Bethesda, Maryland 20892-7982
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

December 20, 2019

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Fassimile: (301) 402-7065

Re: Animal Welfare Assurance #A3410-01 (OLAW Case 7F) Ref: ACR#: 11-19-2

Dr. Terry Magnuson Vice Chancellor for Research University of North Carolina at Chapel Hill Campus Box 4000, (b) (4) South Building Chapel Hill, NC 27599-4000

Dear Dr. Magnuson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 18, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of North Carolina at Chapel Hill, following up on an initial telephone report on November 21, 2019. According to the information provided, OLAW understands that on ten separate occasions, expired analgesic was used on mice.

The corrective action consisted of implementing use of the colored sticker method indicating month and year of expiration, using standard notation for each surgical procedure, and clearly documenting expiration dates.

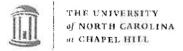
Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. The Institutional Animal Care and Use Committee may wish to consider extending the corrective actions proposed for preventing use of expired drugs to the entire program to prevent similar problems elsewhere. Remember to always include the species involved in the noncompliance reports. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M. Deputy Director Office of Laboratory Animal Welfare

cc: IACUC Chair Director of Animal Care and Use IACUC Training & Compliance Manager



#### UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

## OFFICE OF ANIMAL CARE AND USE

SUITE 1140 BIOINFORMATICS BUILDING T 919-966-5569 CAMPUS BOX 7193 CHAPEL HILL, NC 27599-7115

F 919-966-8429 incuc@med.unc.edu

# IACUC Animal Concern Report (ACR)

PHS Assurance #: D16-00256 (A3410-01)

Part I of this report serves to record preliminary information as it was presented to the Animal Concern Subcommittee (ACS) and includes ACS recommendations to the IACUC. Part I! contains the IACUC's final recommendation to the Institutional Official (IO). This report is not final until Part II is signed and dated by the IO.

Acronyms: Division of Comparative Medicine (DCM) Principal Investigator (PI) Office of Animal Care and Use (OACU) Laboratory Animal Coordinator (LAC)		Training and Compliance Coordinator (T Training and Compliance Team (T&C) Training and Compliance Manager (TCM Animal Concern Subcommittee (ACS)	
ACR#:	11-19-2	NIH Grant #: n/a	
Reported by:	T&C	Recorded by: T&C	

Verbal: Written: X Complainant wishes to remain anonymous: ⊠ No Yes

#### Part I: Animal Concern Subcommittee (ACS) Report

- 1) Concern/Allegation: Use of expired drugs as an anesthetic agent.
- 2) Summary of Events: During a semiannual laboratory inspection, Inspectors noted that expired Buprenorphine was used on 10 separate occasions.

# Principal Investigator (PI) Response:

The PI acknowledged the error and planned to utilize standardized annotations for each surgical procedure and better document expiration dates.

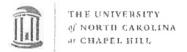
3) Findings of Fact, Conclusions, and ACS Recommendations:

## Standards:

OLAW FAQs Section F5

"The use of expired pharmaceuticals, biologics, and supplies is not consistent with acceptable veterinary practice or adequate veterinary care. Euthanasia, anesthesia and analgesia agents should not be used beyond their expiration date, even if a procedure is terminal. Other expired materials should not be used unless the manufacturer verifies efficacy beyond the expiration date, or the investigator is able to document to the satisfaction of the IACUC that such use would not negatively impact animal welfare or compromise the validity of the study. The veterinarian and IACUC must maintain control over the use of expired medical materials in order to meet their responsibilities to avoid or minimize discomfort, pain or distress to animals."

On page 122 the Guide indicates:



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"Agents that provide anesthesia and analgesia must be used before their expiration dates and should be acquired, stored, their use recorded, and disposed of legally and safely."

a) Subcommittee Recommendations: OACU reported this incident to the ACS on November 18, 2019. The PI/DCM investigated the issue of CONCERN and provided proposed actions to be taken to prevent future occurrences.

All ACS members agreed that the PI's proposed actions were satisfactory, but that a more detailed plan for labeling bottles was necessary. They also agreed that no sanctions were warranted and that it should be reported to OLAW. NIH funds were not used to support this project.

The PI responded to the request for additional details for labeling bottles by implementing colored stickers to designate the year and month of expiration.									
-	Required Repo	Reported to OLA	Y	_MC[ ′es ⊠	No	1/21	_		
Part II: IACUC Conclusion and Report to Institutional Official									
<ol> <li>IACUC Meeting Date and Closure: The IACUC met on December 3, 2019 and voted to accept the ACS recommendations.</li> </ol>									
2) Additional Requirement(s): N/A									
3)	IACUC Vote:	Reportable  Unanimous  Closed  NIH Reimbursem	Not Repor Minority O Pending ent Required	pinion _	] ] ] Yes	□ No	⊠ N	A	
				(b) (6	5)				
Terry Magnuson, Ph.D.						12/18/1	9		

Signature

CC: Principal Investigator OACU Training and Compliance Coordinators and Director Associate Vice Chancellor for Research Office of University Counsel IACUC Chair

Institutional Official

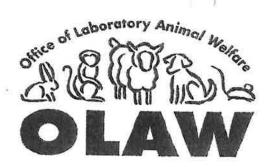
December 2019 IACUC Meeting Updates:

**Date** 

# Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD) Sent: Wednesday, December 18, 2019 3:59 PM (b) (6) Wolff, Axel (NIH/OD) [E]; OLAW Division of Compliance Oversight To: (NIH/OD) (b) (6) Cc: Subject: RE: ACR 11-19-2 Thank you for this report. We will send an official response soon. Best regards, Brent Morse Brent C. Morse, DVM, DACLAM Director Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender. From: Sent: Wednesday, December 18, 2019 3:22 PM To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> (b)(6)Cc: Subject: ACR 11-19-2 Dear Dr. Wolff, The IACUC met on December 3, 2019 and reviewed Animal Concern 11-19-2. The IACUC voted unanimously to accept the subcommittee's recommendations and close this case. A copy of the Final report for this ACR is attached. Please let me know if you have any questions or concerns. Thank you, and happy holidays. (b) (6)

(b) (б)



# **Initial Report of Noncompliance**

By: Ou

Date: $11/2/19$ Time: $1:35$							
Name of Person reporting:  Telephone #:  Fax #:  Email:							
Name of Institution: Assurance number:  1							
Did incident involve PHS funded activity? Funding component: Was funding component contacted (if necessary):							
What happened?  Expired burger enoughing used in mice							
Species involved: Mouse Personnel involved: Later Staff Dates and times: Animal deaths:							
Projected plan and schedule for corréction/prevention (if known):  Send out paley info to all PIS							
Projected submission to OLAW of final report from Institutional Official:							
OFFICE USE ONLY Case #							